UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,330	03/07/2007	Thomas A. Osborne	8627/1247 (PA-5573-PCT/US	3188

48004 7590 07/12/2011

BRINKS HOFER GILSON & LIONE/INDY/COOK
BRINKS HOFER GILSON & LIONE
CAPITAL CENTER, SUITE 1100
201 NORTH ILLINOIS STREET
INDIANAPOLIS, IN 46204-4220

EXAMINER	
PIERY, MICHAEL T	
ART UNIT	PAPER NUMBER
1742	
MAIL DATE	DELIVERY MODE
07/12/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/581,330
Filing Date: March 07, 2007
Appellant(s): OSBORNE, THOMAS A.

Lawrence A. Steward
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 21 April 2011 appealing from the Office action mailed 24 November 2010.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

1, 2, 4, 6-8, 10 and 21-33

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN

REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

6,508,806	Hoste	01-2003
EP 0662385	van Muiden	07-1995
6,171,295	Garabedian et al.	01-2001

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

2. Claims 1, 2, 4, 6-8, 10, 21-30 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoste (US 6,508,806) in view of van Muiden (EP 0662385).

Regarding claim 1, Hoste teaches a method of making an introducer sheath including: positioning a coil over a mandrel (column 4, lines 49-60), positioning a second reinforcing member over the coil where the second reinforcing member has a braid configuration (figure 4), positioning a heat shrink tube over the assembly and heating the material cause the heat shrink material to shrink (column 5, line 54-column 6, line 3). Hoste does not explicitly teach positioning two sleeves with striped extrusions on the coil. Van Muiden, however, teaches it is known to form reinforcing members by positioning a first polymeric sleeve with a striped helical pattern over a mandrel and positioning a second polymeric sleeve with a striped helical pattern over the first sleeve to define a braid-like configuration (column 4, lines 25-44). It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the braid of Hoste with the two helical striped sleeves forming a braid of van Muiden because the configuration taught by van Muiden provides good compression resistance and reliable torsion stiffness (van Muiden: column 1, lines 28-30) desired properties of Hoste (Hoste: column 2, lines 52-55). The examiner interprets that the shrink jacket process of Hoste when modified by van Muiden would form an assembly where the sleeves are melted together to obtain a braid configuration. Van Muiden further teaches it is desirable for the shaped bands of material to achieve a good bond (column 4, lines 32-35).

Regarding claim 2, Hoste does not explicitly teach multiple sleeves with helical stripes. However, van Muiden teaches the sleeves have a striped helical pattern (figure 4). It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the sleeve

of Hoste with the two helical striped sleeves of van Muiden because the configuration taught by van Muiden provides good compression resistance and reliable torsion stiffness (column 1, lines 28-30) desired properties of Hoste.

Regarding claim 4, Hoste does not explicitly teach multiple sleeves with helical stripes. However, van Muiden teaches the stripes extend from the outer surface to the inner surface of both sleeves (figure 4). It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the sleeve of Hoste with the two helical striped sleeves of van Muiden because the configuration taught by van Muiden provides good compression resistance and reliable torsion stiffness (column 1, lines 28-30) desired properties of Hoste .

Regarding claim 6, Hoste does not explicitly teach sleeves are coextruded with stripes. However, van Muiden teaches the sleeves are co-extruded with the stripes (column 2, lines 43-47). It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the sleeve of Hoste with the two helical striped sleeves of van Muiden because the configuration taught by van Muiden provides good compression resistance and reliable torsion stiffness (column 1, lines 28-30) desired properties of Hoste.

Regarding claims 7 and 8, Hoste teaches it is known to place an inner liner material over a mandrel then place a coil over the inner liner then bond a sleeve to the coil and heating the layers in a shrink tube (column 4, lines 36-48).

Regarding claim 10, Hoste does not explicitly teach a sleeve comprises two segments. However, van Muiden teaches forming a sleeve with two sleeve segments, where one has a higher durometer than the other (column 1, lines 25-34). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Hoste to include multiple segments

because the multiple segments allow for variation in properties, such as stiffness, along the length of the catheter.

Regarding claim 21, Hoste teaches a method of making an introducer sheath including positioning a liner over a mandrel (figure 2, #22), positioning a coil over the liner (column 4, lines 49-60), positioning a second reinforcing member over the coil where the second reinforcing member has a braid configuration (figure 4), positioning a heat shrink tube over the assembly and heating the material cause the heat shrink material to shrink (column 5, line 54-column 6, line 3). Hoste does not explicitly teach positioning two sleeves with striped extrusions on the coil. Van Muiden, however, teaches it is known to form reinforcing members by positioning a first polymeric sleeve with a striped helical pattern over a mandrel and positioning a second polymeric sleeve with a striped helical pattern over the first sleeve to define a braid-like configuration (column 4, lines 25-44). It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the braid of Hoste with the two helical striped sleeves forming a braid of van Muiden because the configuration taught by van Muiden provides good compression resistance and reliable torsion stiffness (column 1, lines 28-30) desired properties of Hoste (column 2, lines 52-55). The examiner interprets that the shrink jacket process of Hoste when modified by van Muiden would form an assembly where the sleeves are melted together to obtain a braid configuration. Van Muiden further teaches it is desirable for the shaped bands of material to achieve a good bond (column 4, lines 32-35).

Regarding claim 22, Hoste teaches removing the mandrel and heat shrinking sleeve (column 4, lines 45-48).

Regarding claim 23, Hoste does not explicitly teach multiple sleeves with helical stripes. However, van Muiden teaches the stripes extend from the outer surface to the inner surface of both sleeves (figure 4). It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the sleeve of Hoste with the two helical striped sleeves of van Muiden because the configuration taught by van Muiden provides good compression resistance and reliable torsion stiffness (column 1, lines 28-30) desired properties of Hoste.

Regarding claim 24, Hoste does not explicitly teach multiple sleeves with helical stripes; however, van Muiden teaches two sleeves with helical patterns. It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the sleeve of Hoste with the two helical striped sleeves of van Muiden because the configuration taught by van Muiden provides good compression resistance and reliable torsion stiffness (column 1, lines 28-30) desired properties of Hoste.

Regarding claim 25, Hoste does not explicitly teach multiple sleeves with helical stripes; however, van Muiden teaches the sleeves are coextruded with the striped extrusion (column 4, lines 25-38). It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the sleeve of Hoste with the two helical striped sleeves of van Muiden because the configuration taught by van Muiden provides good compression resistance and reliable torsion stiffness (column 1, lines 28-30) desired properties of Hoste.

Regarding claims 26 and 27, Hoste does not explicitly teach multiple sleeves with helical stripes; however, van Muiden teaches it is known to vary the composition and pattern of extrudates in order to vary the stiffness and physical properties of the sheath. It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the sleeve of

Hoste with the two helical striped sleeves of van Muiden because the configuration taught by van Muiden provides good compression resistance and reliable torsion stiffness (column 1, lines 28-30) desired properties of Hoste.

Regarding claim 28, Hoste teaches the sleeve is formed by polyamide material (column 5, lines 54-59).

Regarding claim 29, Hoste does not explicitly teach multiple sleeves with helical stripes; however, van Muiden teaches it is known to form sleeves of polyamide material with a higher durometer stripe (column 5, lines 10-15). It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the sleeve of Hoste with the two helical striped sleeves of van Muiden because the configuration taught by van Muiden provides good compression resistance and reliable torsion stiffness (column 1, lines 28-30) desired properties of Hoste.

Regarding claim 30, Hoste does not explicitly teach multiple sleeves with helical stripes; however, van Muiden teaches forming the sleeves by a stripe extrusion process (column 4, lines 1-20). It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the sleeve of Hoste with the two helical striped sleeves of van Muiden because the configuration taught by van Muiden provides good compression resistance and reliable torsion stiffness (column 1, lines 28-30) desired properties of Hoste.

Regarding claim 33, Hoste does not explicitly teach the claimed thickness range. It would have been obvious, however, to one of ordinary skill in the art at the time of the invention to modify the process of Hoste to use a wall thickness of 0.010 inch because it has been held that

where the general conditions of a claim are disclosed, finding the optimum workable range is *prima facie* obvious (MPEP 2144).

3. Claims 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoste (US 6,508,806) in view of van Muiden (EP 0662385), as applied above to claims 21 and 27, and further in view of Garabedian et al. (US 6,171,295).

The modified Hoste reference teaches the method of claims 21 and 27, as applied above.

Regarding claims 31 and 32, Hoste does not explicitly teach the lower durometer sleeve includes a radiopaque material. Garabedian, however, teaches it is known to form catheters using radiopaque material (column 1, lines 29-32). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the process of Hoste to use radiopaque material because the material allows the physician to monitor the movement of the catheter (column 1, lines 31-40).

(10) Response to Argument

Appellant argues that the references fail to teach a sheath capable of enhanced torqueability and kink resistance while maintaining a thin sheath wall because van Muiden teaches the integrity of the two layers is maintained and Hoste teaches discrete stacked reinforcing members. Both references teach a thin walled catheter is desirable (column 2, lines 21-29 of Hoste; column 1, lines 16-19 of van Muiden). Further, there is no indication that substituting the braid of van Muiden for the braid of Hoste would increase the thickness to a point where the catheter would be undesirable.

Appellant argues that the references do not teach the sleeves are melted together in a manner such that the resulting sheath outer layer includes the superposed striped extrusions that define the braided reinforcement. The examiner disagrees. Hoste teaches using a heat shrink jacket process to impregnate the wire structure (column 5, line 54-column 6, line 13). The heat shrink process causes the polymer to melt in order to impregnate the wire structure. When this process is applied to Hoste as modified by van Muiden, the polymeric sleeves melt together. This heating step is consistent with van Muiden's desire for the layers to possess a "good bond" (column 4, lines 34-35) because the two layers melted together would possess this desirable "good bond."

Appellant argues that the suggestion in the references of the desirability of minimal wall thickness teaches away from incorporating the layers of van Muiden into the configuration of Hoste because using two sleeves does not advance the desire of maintaining low wall thickness. The examiner disagrees. Hoste's teaching is not only that the catheter has a small wall thickness but the catheter also has certain structural properties (column 2, lines 54-56). Hoste's teaching is to optimize the wall thickness in order to obtain the certain structural properties for the end use of the catheter, not just to find the smallest possible wall thickness. The two layers of van Muiden are not a teaching away from Hoste because van Muiden has found the optimal wall thickness given the desired properties of the catheter. Further, there is no indication that substituting the braid of van Muiden for the braid of Hoste would increase the thickness to a point where the catheter would be undesirable.

Appellant argues that Hoste cannot teach the heating step that causes the sleeves to melt together to form the outer tubular layer. The examiner disagrees. Hoste teaches using a heat

shrink jacket process to impregnate the wire structure (column 5, line 54-column 6, line 13). The heat shrink process causes the polymer to melt in order to impregnate the wire structure. When this process is applied to Hoste as modified by van Muiden, the polymeric sleeves melt together. This heating step is consistent with van Muiden's desire for the layers to possess a "good bond" (column 4, lines 34-35) because the two layers melted together would possess this desirable "good bond."

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Michael T Piery/

Examiner, Art Unit 1742

/Christina Johnson/

Supervisory Patent Examiner, Art Unit 1742

Conferees:

Christina Johnson /caj/

/David A. Simmons/

Quality Assurance Specialist, Tech Center 1700